



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

September 2, 2015

Simple Science, LLC  
Mr. Eoin Croke  
CTO  
5555 West 78<sup>th</sup> Street Suite M  
Edina, Minnesota 55439

Re: K142592  
Trade/Device Name: CleanSmart (TM) Wound Cleanser  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: August 20, 2015  
Received: August 27, 2015

Dear Mr. Croke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142592

Device Name

CleanSmart™ Wound Cleanser

Indications for Use (Describe)

Over-the-Counter Use:

For management of minor skin abrasions, minor lacerations, minor irritations, minor cuts, minor burns and intact skin.

Prescription Use:

For management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first-and second-degree burns, grafted and donor sites, and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## **K142592 510(k) Summary (r4)**

**1. Submitter's Name and Address**

Simple Science, LLC.  
5555 W 78th St STE M  
Edina, MN 55439

**2. Submitter's Contact Person**

Eoin Croke  
(612) 367-4540  
eoin.croke@simplesciencecellc.com

**3. Date of 510(k) Summary Preparation:**

1<sup>st</sup> September 2015

**4. Device Name (Proprietary)**

CleanSmart™ Wound Cleanser

**5. Common Name**

Wound was Solution

**6. Classification Name**

Wound Dressing, Drug

**7. Device Class**

Unclassified

**8. Device Code**

FRO

**9. Legally Marketed Device for substantial equivalence comparison:**

CleanSmart™ Wound Cleanser is substantially equivalent to the following cleared predicate devices:

- 1) Nixall™ Wound and Skin Care (OTC and Professional use) manufactured by Seriously Clean LTD, cleared for distribution under 510(k) K113693 (11/12/2012)
- 2) Puracyn Plus™ Skin and Wound Care (OTC and Professional use) manufactured by Innovacyn, Inc, cleared for distribution under 510(k) K133542 (28/4/2014)
- 3) Oculus Puracyn™ Skin and Wound Cleanser with Preservatives manufactured by Oculus Innovative Sciences Inc., cleared for distribution under 510(k) K090206 (02/06/2009)
- 4) Vashe® Wound Therapy Solution (OTC use) manufactured by PuriCore, Inc. cleared for distribution under 510(k) K093697 (13/04/2010)

## 10. Description of Device

CleanSmart™ Wound Cleanser is a clear hypotonic solution topically applied to skin and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. CleanSmart™ Wound Cleanser contains the following ingredients: Ionized water (99.927%), Sodium chloride (0.06%), Hypochlorous acid (0.011%) and hypochlorite Ion (0.002%). CleanSmart™ Wound Cleanser will be supplied in Polyethylene terephthalate (PET) bottles of various volumes (2 oz, 8 oz, 16 oz, 23 oz) with spray inserts / caps.

## 11. Intended Use of Device

CleanSmart™ Wound Cleanser is intended for over-the-counter (OTC) and professional use as follows:

- **For Over-the-Counter Use:** For management of minor skin abrasions, minor lacerations, minor irritations, minor cuts, minor burns and intact skin.
- **Prescription Use:** For management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first-and second-degree burns, grafted and donor sites, and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

These indications are similar to that of the predicate devices.

## 12. Device Technological Characteristics

CleanSmart™ Wound Cleanser is a clear hypotonic solution to aid in the removal of debris and foreign material from the application site. This is accomplished through the flow of the solution moving across the application site with or without the assistance of a suitable wound dressing. CleanSmart™ Wound Cleanser solution contains a preservative that inhibits the growth of microorganisms within the solution. CleanSmart™ Wound Cleanser is manufactured under Good Manufacturing Practices (GMP) guidelines.

## 13. Manufacturing

CleanSmart™ Wound Cleanser will be manufactured under the guidelines of current Good Manufacturing Practices (cGMPs) and according to the established manufacturing, quality, and product specifications. Process validations have been completed for this device, and filling process parameters have been qualified. Manufacturing controls have been established and implemented to address the identified risk factors based on the criticality of the failure mode. Established cGMPs will assure the device manufactured by Simple Science, LLC.

meets all the established specifications prior to release, and is substantially equivalent to its predicates.

#### **14. Performance Testing**

CleanSmart™ Wound Cleanser has been subjected to ISO 10993 biocompatibility studies (cytotoxicity, sensitization, irritation) to demonstrate that the device is as safe and as effective as its predicate devices. The preservative effectiveness has been supported by USP <51> testing. Additionally, Test results have demonstrated preservative effectiveness against the following bacteria in solution, *Proteus mirabilis* (ATCC- 25933), *Serratia marcescens* (ATCC-8100), antibiotic resistant Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC-43300), Vancomycin-resistant *Enterococcus faecalis* (VRE) (ATCC-700221), and *Acinetobacter baumannii* (ATCC 19606). The results of the stability study demonstrate that the product is stable and effective for the entire shelf life of 12Months.

#### **15. Substantial equivalence conclusion**

As discussed in this 510(k) submission, CleanSmart™ Wound Cleanser is similar in function and has the same intended use as the predicate devices Nixall™ Wound and Skin Care, 510(k) K113693, Puracyn Plus™ Skin and Wound Care, 510(k) K133542, Puracyn™ Skin and Wound Cleanser with Preservatives, 510(k) K090206, and Vashe® Wound Therapy Solution. 510(k) K093697. The safety evaluation meets the requirements as detailed by USP and ISO.

On the basis of the information presented in this 510(k) submission, Simple Science, LLC. concludes a) that CleanSmart™ Wound Cleanser is substantially equivalent to the predicate devices, as it has the same intended use as the predicates; and b) demonstrates that the device is at least as safe and as effective as the legally marketed predicate devices.